JAN 0 7 2003

510(K) SUMMARY

AccuLeaf

510(k) Number K 02/338

Applicant's Name:

Direx Systems Corp.
11 Mercer Road, Natick Business Park
Natick, MA 01760
United States of America

Tel: (508) 6510900
Fax: (508) 6518125

Contact Person:

Larisa Gershtein
Tel: (508) 6510900
Fax: (508) 6518125

Trade Name:

AccuKnife

Model:

AccuLeaf

Classification Name:

Medical Linear Accelerator

Classification:

The FDA has classified this type of devices as class II (product code 90 IYE, Regulation No. 892.5050) and they are reviewed by the Radiology Panel.

Predicate Devices:

- BrainLAB Med, GmbH's Micro-Multi Leaf Collimator (K970586)

Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, *AccuLeaf* complies with the following voluntary standards: IEC 60601-1 (1990) +A1 (1993) +A2 (1995); IEC 60601-1-1 (2000); IEC 60601-1-2 (1993); IEC 60601-1-4 (2000).

Intended Use:

The *AccuLeaf* is intended to assist the radiation oncologist in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation.

The *AccuLeaf* enables irregular fields treatments to be performed with finely shaped patterns. In this application the *AccuLeaf* performs the same function as customized beam shaping blocks, and circular or cut blocks collimators, which have been used for many years

Device Description:

AccuLeaf is a LINAC based Micro-Multi-Leaf-Collimator (MMLC), used during both conformal stereotactic radiotherapy and conformal stereotactic radiosurgery. It enables shaping the LINAC beam according to tumor shape and clinical demands. The device is composed of the MMLC module, the LINAC interface module, the Workstation (with *AccuLeaf*-CS), and the Distribution module. The device is operated in conjunction with a LINAC, its treatment couch, a data file that contains the desired aperture parameters, and any additional equipment required during radiotherapy/ radiosurgery.

Substantial Equivalence:

Based on validations and performance testing results, Direx Systems Corp. believes that *AccuLeaf* is substantially equivalent to the predicate device cited above without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

Ms. Larisa Gershtein
QA Manager
DiREX Systems Corp.
11 Mercer Road
NATICK MA 01760

Re: K021338
Trade/Device Name: AccuLeaf
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 7, 2002
Received: October 11, 2002

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021338

Device Name:

AccuLeaf

Indications for Use:

The *AccuLeaf* is intended to assist the radiation oncologist in the delivery of radiation to well defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation. The *AccuLeaf* enables irregular fields treatments to be performed with finely shaped patterns. In this application the *AccuLeaf* performs the same function as customized beam shaping blocks, and circular or cut blocks collimators, which have been used for many years

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510(k) Number K021338

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

David A. Lejeune

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021338